K061923

AUG 25 2006

510(k) Summary for the
Dimension Vista™ System Enzyme 1 Calibrator
(ENZ 1 CAL – KC310)

A. 510(k) Number:

B. Analytes: Amylase (AMY), Gamma-Glutamyl Transferase (GGT), Lactate Dehydrogenase (LDH), Lipase (LIP), and Pseudocholinesterase (PCHE).

C. Type of Test: Calibrator Material

D. Applicant: Dade Behring Inc., P.O. Box 6101, Newark, DE 19714-6101
Victor M. Carrio, Regulatory Affairs and Compliance Manager
Office: (302) 631-0376 Fax: (302) 631-6299

E. Proprietary and Established Names:

Dimension Vista™ System Enzyme 1 Calibrator
(ENZ 1 Cal – KC310)

F. Regulatory Information:

1. Regulation section: 21 CFR § 862-1150 – Calibrator
2. Classification: Class II
3. Product Code: JIX – Calibrator, Multi-Analyte Mixture
4. Panel: Clinical Chemistry

G. Intended Use: The ENZ 1 CAL is an *in vitro* diagnostic product for the calibration of Amylase (AMY), Gamma-Glutamyl Transferase (GGT), Lactate Dehydrogenase (LDH), Lipase (LIP), and Pseudocholinesterase (PCHE) methods on the Dimension Vista™ System.

H. Device Description:

ENZ 1 CAL is a liquid, multi-analyte, bovine serum albumin based product containing amylase (human saliva), gamma-glutamyl transferase (bovine kidney), lactate dehydrogenase (chicken heart), lipase (porcine pancreas), and pseudocholinesterase (horse serum). The kit consists of six vials, three vials of Calibrator A, and three vials of Calibrator B which are ready for use (no preparation is required). The volume per vial is 2.5 mL.

I. Substantial Equivalence Information:

	Device	Predicate Devices		
Item	**Dimension Vista™ System Enzyme 1 Calibrator**	**Dimension® Enzyme Verifier K860021**	**Dimension® Lipase Calibrator K952815**	**Dimension® PCHE Verifier K883891**
Intended Use	The ENZ 1 CAL is an *in vitro* diagnostic product for the calibration of Amylase (AMY), Gamma-Glutamyl Transferase (GGT), Lactate Dehydrogenase (LDH), Lipase (LIP), and Pseudocholinesterase (PCHE) methods on the Dimension Vista™ System.	Enzyme Verifier is an *in vitro* diagnostic product to be used to verify Alkaline Phosphatase (ALP), **Amylase (AMY), G-Glutamyl Transferase (GGT),** Aspartame Aminotransferase (AST), Alanine Aminotransferase (ALT) and **Lactic Dehydrogenase (LDH)** method performance on the Dimension® clinical chemistry system.	The Lipase Calibrator is an *in vitro* diagnostic product to be used to calibrate the Dimension® clinical chemistry systems for the **Lipase (LIP)** method.	The Dimension® Pseudocholinesterase Verifier is an *in vitro* diagnostic product to be used to verify the Dimension® clinical chemistry system for the **Pseudocholinesterase (PCHE)** method.
Analytes	Amylase (AMY) Gamma-Glutamyl Transferase (GGT) Lactate Dehydrogenase (LDH) Lipase (LIP) Pseudocholinesterase (PCHE).	Alkaline Phosphatase (ALP) **Amylase (AMY)** **Gamma-Glutamyl Transferase (GGT)** Aspartame Aminotransferase (AST) Alanine Aminotransferase (ALT) **Lactic Dehydrogenase (LDH)**	**Lipase (LIP).**	**Pseudocholinesterase (PCHE).**
Form	Liquid.	Lyophilized.	Lyophilized.	Lyophilized.
Traceability	Master Pool, Dimension® clinical chemistry system values.	Master Pool, Dimension® clinical chemistry system values.	Master Pool, Dimension® clinical chemistry system values.	Master Pool, Dimension® clinical chemistry system values.
Matrix	Bovine serum base with amylase (human saliva), GGT (bovine kidney),	Human serum base with amylase (porcine pancreas), GGT (bovine kidney), and LDH (bovine heart).	Human serum with lipase (porcine pancreas).	Human serum and bovine serum albumin base product.

	Device	Predicate Devices		
Item	**Dimension Vista™ System Enzyme 1 Calibrator**	**Dimension® Enzyme Verifier K860021**	**Dimension® Lipase Calibrator K952815**	**Dimension® PCHE Verifier K883891**
	LDH (chicken heart), lipase (porcine pancreas), and PCHE (horse serum).			
Number of Levels	Two levels.	Three levels.	Three levels.	Three levels.

J. Standard/Guidance Document Referenced:

1. Guidance: Guidance for Industry - Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators; Final, 02/22/1999
Guidance for Industry and FDA Staff - Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use, 11/30/2004

2. Standards: CEN 13640 Stability testing of In-Vitro Diagnostic Devices
ISO 14971:2000 Medical devices -Application of risk management to medical devices

K. Performance Characteristics:

1. Stability: Target shelf life for the Dimension Vista™ Enzyme 1 Calibrator is 12 months. Calibrator shelf life is determined by comparing results of the product stored at 4°C with control stored at -70°C. The method is calibrated from this stored material. The 4°C material values are recovered versus the calibration. Recovery versus time is monitored and percent change over time is determined where the allowable shelf life percent change should be ≤ 7 % for lipase and ≤ 5 % for amylase, gamma-glutamyl transferase, lactate dehydrogenase, and pseudocholinesterase. Shelf-life stability (expiration) dating assignment at commercialization reflects the real-time data on file at Dade Behring, Inc.
A vial punctured by the instrument and stored on board has a seven day stability claim.
An open vial not on instrument, but recapped and stored in a refrigerator has a stability claim of 31 days.

   For testing, vials are opened /punctured on day zero. A quantity sufficient for multiple calibrations is removed and the vials are recapped and stored at 2 – 8 °C. Opened/punctured vials are tested on days 3, 8, 15, 22, and 32 versus freshly opened vials.

2. Traceability: The assigned values of the Enzyme 1 Calibrator are traceable to Master Pool, Dimension® clinical chemistry system.

3. Bottle Value Assignment:

   Bovine serum albumin (BSA) base is used as Level 1 for AMY, GGT, LDH, PCHE and LIP and stored at -70°C.
AMY, GGT, LDH and PCHE are added gravimetrically to BSA base to target concentrations for levels 2 and 3 and stored at -70°C.
Dimension® LIP Master Pools in human serum are used for levels 2, 3 and 4 and stored at 2 - 8°C.

Master Pool level 1 of BSA base is assigned value 0 U/L.
LIP Master Pool bottle values levels 2, 3, and 4 are assigned on multiple instruments calibrated with LIP Anchor Pool. The LIP Anchor Pool values are assigned using an external reference system (PBS/Precical®).
AMY, GGT, LDH and PCHE bottle values for levels 2 and 3 are assigned on multiple instruments using fixed coefficients. N > 40 total replicates per level. A previous Master Pool lot is used as a control.
To manufacture Enzyme 1 Calibrator, a stock solution is prepared by gravimetrically adding quantities of AMY, GGT, LDH, LIP, and PCHE to bovine serum albumin base to target concentrations. The stock solution is verified by comparing the recovery of the stock solution versus the Master Pool assigned bottle values. Calculated quantities of the stock solution are added to the bovine serum albumin base to target concentrations to produce the commercial calibrator lot. The concentration of each level is verified to be within acceptable range by using an instrument calibrated with Master Pools. The final bottle value is assigned to each level and verified on multiple instruments for N > 40 total replicates using a released commercial lot of calibrator as a control.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 25 2006

Mr. Victor M. Carrio
Dade Behring, Inc.
P.O. Box 6101
Newark, DE 19714

Re: k061923
Trade/Device Name: Dimension Vista™ Enzyme 1 Calibrator (KC310)
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIX
Dated: July 6, 2006
Received: July 7, 2006

Dear Mr. Carrio:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

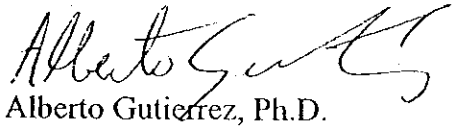
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

510(k) Number (if known):

Device Name: K061923

Dimension Vista™ Enzyme 1 Calibrator (KC310)

Indications for Use:

The ENZ 1 CAL is an *in vitro* diagnostic product for the calibration of Amylase (AMY), Gamma-Glutamyl Transferase (GGT), Lactate Dehydrogenase (LDH), Lipase (LIP), and Pseudocholinesterase (PCHE) methods on the Dimension Vista™ System.

Prescription Use __X__ **AND/OR** **Over-the-counter Use** _____
(Per 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of -In Vitro Diagnostic Devices (OIVD)

Carol Benson
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K061923